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Health Care Epidemiology: Evidence-Based Practice

Few terms in health care elicit as much debate as *evidence-based medicine* (EBM)/*evidence-based practice* (EBP). Many clinicians and patients equate EBP with cookbook medicine, lack of choice, ignoring clinical differences and patient preferences, and cost-cutting.[1] However, the goal of EPB is to increase the probability of desired health outcomes by integrating scientific evidence, clinical expertise, and patient preferences as clinical decisions are made.[2]

The goal of EBP is consistent with the overall purpose of quality health care adopted by the Institute of Medicine. That IOM definition of quality health care is " the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with professional knowledge" (p. 2).[3]

This ERIC Notebook reviews the principal concepts, reasons for, and steps involved in EBP. In addition, there is a discussion of reliable sources of the main types of documents used to provide information needed to practice evidence-based care, systematic reviews and clinical practice guidelines.

What is evidence-based practice?

A Dictionary of Epidemiology sponsored by the International Epidemiology Association defines *evidence-based medicine [practice]* as (p. 64)[4]:

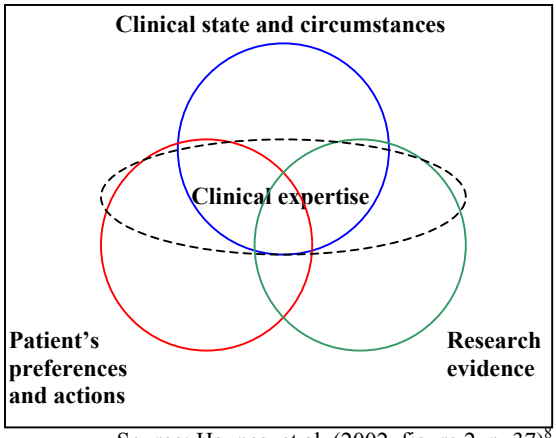
> The consistent use of current best evidence derived from published clinical and epidemiologic research in management or patients, with attention to the balance or risks and benefits of diagnostic tests and alternative treatments, taking account of each patient's unique circumstances, including baseline risk, comorbid conditions, and personal preferences.

EBP/EBM does not seek to replace the role of individual clinical expertise. Rather, the goal is to integrate "individual clinical expertise with the best available external clinical evidence from systematic research" (p. 71).[2] Further, EBP involves integrating the individual preferences of patients into treatment decisions that attempt to balance potential benefits and consequences of health care interventions.[5, 6]

Sackett and Rosenberg identify EBM as a construct that encompasses these interrelated concepts (quoted from p. 620)[7]:

1. Our clinical and other health care decisions should be based on the best patient- and population-based as well as laboratory-based evidence.
2. The problem determines the nature and source of evidence to be sought, rather than our habits, protocols or traditions.
3. Identifying the best evidence calls for the integration of epidemiological and biostatistical ways of thinking with those derived from pathophysiology and our personal experience.
4. The conclusions of this search and critical appraisal of evidence are worthwhile only if they are translated into actions that affect our patients.
5. We should continuously evaluate our performance in applying these ideas.

Evidence-Based Clinical Decisions



Source: Haynes, et al. (2002, figure 2, p. 37)[8]

Why Evidence-Based Practice?

The need for EBP is demonstrated by two topics addressed in issue 24 of *ERIC Notebook*. Unexplained geographic variation in the content of health care – such as surgical interventions

(e.g. hysterectomy, tympanostomy rates) and use of one treatment over another (e.g. hemodialysis vs. peritoneal dialysis) – have been document for more than 30 years.[9, 10] Some variation can be expected based on clinical circumstances, available resources, and patient preferences. However, these legitimate reasons do not account for much of the observed difference.[11]

Significant variation has been noted between physicians who receive identical information about patients and between decisions made by the same provider who reviews identical clinical situations at different times.[11] The issue of variance among and within providers is closely linked to the difficulty people have in obtaining and processing complex information that must be considered when making a clinical decision.[12, 13]

When different clinical decisions are not based on expected reasons such as clinical circumstances, patient preferences, and available resources, it is not possible for all of the decisions to be ones that would lead to the greatest possibility of a desired outcome. While no system for decision making can be expected to be perfect, EBP attempts to reduce inappropriate variations in care and increase the probability of desired outcomes. EBP strives to incorporate the best available scientific evidence and improve the ability of clinicians to obtain and process clinical information.

EBP Addresses Three Forms of Inappropriate Use of Services

The ultimate goal of EBP is to optimize patient outcomes while minimizing inappropriate use of health care services. The Institute of Medicine has identified three major types of quality deficiencies that can be addressed with EBP.[14, 15]

Overuse is providing care that is not appropriate (i.e. providing too much care).[14] Appropriate care requires that for patients with particular clinical and personal characteristics, the expected benefits of an intervention outweigh the potential negative consequences (e.g. side effects) by a "wide enough margin to make the intervention or service worth doing" (p. 232).[16] An example of overuse is the possibility that many hysterectomies are inapparently recommended.[17]

Underuse is the failure to utilize interventions that would have produced desired health outcomes (providing too little care).[14] In other words, appropriate care is not provided. Failure to provide necessary care, a subtype of appropriate care, is especially concerning. "Care is considered necessary if there is a reasonable chance of a nontrivial benefit to the patient and if it would be improper not to provide the care" (p. 233).[16] For many years, there has been great concern expressed over failure to provide services such as proper follow-up care for myocardial infarctions, immunizations, and monitoring chronic illness.[18]

Misuse occurs when the appropriate care is provided, but the patient does not receive full benefit of the care or preventable complications occur (providing care in the wrong way).[14] Misuse is also referred to as an error, "failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning)" (p. 28).[19] An example of misuse is medication errors occurring during the introduction of new treatments.[20]

Necessary Steps in the Practice of EBP

EBP is a process aimed at improving the care of patients. Different groups or individuals may be more or less involved in completing each step of the process. For example, a professional group may synthesize large bodies of evidence and write guidelines. Individual provider organizations and clinicians need approaches to appraising and selecting guidelines, including consideration of when new research should prompt revision. The following steps summarize a general approach systematically obtaining and weighing evidence to inform care.

1. Use clinically relevant, answerable questions to frame the issues that need to be addressed.

The first step in the practice of EBP is to determine the questions to be answered. The questions should be clinically relevant to your population of patients, answerable, and of an appropriate scope. Patients, problems, interventions, alternative interventions for comparison (when relevant), and outcomes being targeted should be described. The questions drive subsequent steps in the EBP process.[21]

2. Select studies to be reviewed to develop clinical recommendations.

Relevant studies should be systematically identified by use of searchable databases such as MEDLINE (http://www.pubmed.gov), in concert with cross-checking with review articles and experts to confirm the process has been exhaustive.

Studies that do not show statistically significant results are less likely to be published, an issue termed publication bias. It may be necessary to ask expert researchers if they are aware of such studies.[22]

Criteria for including studies in the review of the evidence need to be established. Example criteria include study topic, design, population studied, outcome measures, length of follow-up, and year of publication.[23]

3. Extract the information needed to evaluate studies and synthesize results.

Critical study data should be compiled in a standardized fashion by abstracting the information into a

data collection from. Uniform extraction of quantitative data allows formal synthesis of the evidence.[24]

4. Evaluate the quality of individual studies.

Numerous systems define levels of evidence to be included in practice recommendations. While these have different specifics, they all assign higher levels to studies less likely to be affected by bias.[25] One respected rational for defining levels of evidence is that of the US Preventive Services Task Force (USPSTF). The following levels are based on study design (p. 26)[23]:

I Properly randomized controlled trials
II-1 Well-designed controlled trials without randomization
II-2 Well-designed cohort or case-control analytic studies, preferably from more than one center or research group
II-3 Multiple time series with or without the intervention or dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatments in the 1940's)
III Opinions of respected authorities, based on clinical experience, descriptive studies and case reports, or reports of expert committees

5. Synthesize evidence to draw conclusions.

Traditionally in medicine, much of what has been done has been primarily based on the experience of the individual physician.[11] While clinical experience is important, the conclusions that can be drawn may not be accurate. Reasons for misplaced conclusions include the fact that the individual clinician may not see a representative sample of patients, people tend to place excess emphasis on unusual cases, and the difficulty of synthesizing a large amount of data from different studies.[12, 13]

A **systematic review** is a "review that has been prepared using a systematic approach to minimizing biases and random errors which is documented in a material and methods section" (p. 5).[26] A **meta-analysis** is a type of systematic review in which statistical methods are used to combine study results to produce a single estimate of a treatment effect.[26] It is important for systematic reviews to consider studies that may indicate a negative or neutral, not just positive, effect of an intervention.[22]

6. Write and classify the strength of clinical recommendations.

The results of the systematic review may be used to develop clinical recommendations. The group that writes the recommendations should include people with relevant clinical and research expertise.

The most common way of expressing the recommendations is through a **clinical practice guideline**. This document offers guidance to providers and patients making decisions in specific clinical situations. The goal is to assist in the balancing of benefits, harms, and patient preferences. While guidelines should be followed in most situations, they are intended to be flexible based on clinical circumstances and patient preferences.[6]

The strength of guideline recommendations can be specified based on the quality of evidence and net benefits (how much intervention benefits outweigh harms).[23] The strength of recommendations impacts the level of intended guideline flexibility, which should also be described.[6]

7. Implement the recommendations.

Providers and organizations implement recommendations. This may be the most difficult part of the EBP process.

It is often necessary and appropriate to modify guidelines produced by outside groups to meet the realities of the local environment (e.g. available equipment, staff, or cultural norms). At the same time, it is important not to modify guidelines to the point that they are no longer evidence-based.[27]

Despite the wide availability of practice guidelines, their implementation and related clinician behavior change have proven to be extremely difficult. Reasons for the physicians not using guidelines include lack of awareness of the guideline, lack of familiarity with recommendations, not agreeing with recommendations, not believing it is possible to follow the guideline, not having motivation to change, time limitations, lack of reminders, lack of agreement among guidelines, lack of resources, and organization resistance.[28] Intensive behavior change activities and system supports will be required to implement guidelines.

8. Evaluate the implementation of EBP.

After an EBP system has been implemented, it is necessary to evaluate the use of EBP principles and guidelines.[7] This includes an evaluation of both the use of principles and guidelines by the individual clinician and organization[7] and periodic regular assessment of the need to update practice guidelines.[6]

Selecting Clinical Practice Guidelines

Clinical practice guidelines and systematic reviews are produced by many organizations. Guidelines often do not recommend exactly the same course of care or review the same literature.[29] The following questions may be useful to consider when deciding whether recommendations of a guideline should be adopted:

- What clinical circumstances and outcomes are covered in the guideline?
- Are the clinical circumstances and outcomes important to my/our population of patients?
- Is the guideline aimed at patients similar to those in my/our population of patients?
- How long ago was the guideline developed?
- What group(s) wrote and/or endorsed the guideline?
- Does the organization(s) that wrote the guideline have a bias that may impact recommendations?
- Is it possible to define the strategy authors used to identify and select studies for review?
- Are there important research studies about the area not reviewed by the guideline authors?
- What methods were used to synthesize the evidence?
- How strong is the evidence for recommendations?
- Are the necessary resources (e.g. diagnostic equipment) available to implement the guideline?
- Are instructions concerning guideline flexibility appropriate to the degree of uncertainty about recommendations and range of patient preferences?
- How will the guideline need to be modified to meet the needs of the setting(s) in which it will be used?

Accessing Clinical Practice Guidelines and Systematic Reviews

Below, there is a description of three resources for obtaining guidelines and systematic reviews.

VA Office of Quality and Performance. Many of the Veterans Health Administration clinical practice guidelines are available on the Web site of the VA Office of Quality and Performance (http://www.oqp.med.va.gov). The Web site provides comprehensive presentations of guidelines, recommendation summaries, practice algorithms, pocket guides, performance measures, and related Web links.[30]

National Guideline Clearinghouse. Probably the most extensive source of clinical practice guidelines in the United States is the National Guideline Clearinghouse (http://www.guideline.gov). The NGC is updated weekly by the Agency for Healthcare Research and Quality in partnership with the American Medical Association and American Association of Health Plans.

The Clearinghouse defines guidelines as documents that "contain systematically developed recommendations, strategies, or other information to assist health care decision making in specific clinical circumstances" (p. 1).[31] To be included, guidelines must be the most current version (developed, reviewed, or revised within the last 5 years), have been produced under the supervision of a relevant professional organization, and have been developed using a process that included a verifiable systematic review of evidence from the peer reviewed literature. The NGC includes structured guideline abstracts, links to or information on ordering full guidelines, syntheses of guidelines covering similar topics, the ability to do side-by-side guideline comparisons, and annotated bibliographies on guideline development, structure, implementation, and evaluation. You can either search for or browse guidelines.

You can sign up for the NGC_L discussion list that allows users to exchange information on guideline development, dissemination, implementation, and evaluation. An email alert system can inform users when new or updated guidelines are added to the NGC.[31]

Cochrane Collaboration. Founded in 1993, the Cochrane Collaboration (http://www.cochrane.org) brings together experts on a wide variety of health care topics to systematically review scientific evidence derived from clinical trials. When possible and appropriate, meta-anlyses of trial results are done. Reviews are made available thorough the Cochrane Library (online and CD-ROM versions available), which is updated quarterly. For individuals in the United States, access to the library requires buying a yearly subscription. Review abstracts can be read on the Cochrane Collaboration Web site.[32]

Conclusion

EBP combines the science and art of medicine. By systematically integrating research evidence with considerations of clinical circumstances and patient priorities, clinicians are able to concentrate their expertise on working with patients to make decisions that maximize the likelihood of desired outcomes. Rather than ignoring individual differences, practice guidelines help to focus consideration of individual circumstances on choosing between treatment plans that have the highest probability of producing the best results.

Helpful Web Sites

Cochrane Collaboration
http://www.cochrane.org

Guide to Community Preventive Services
http://www.thecommunityguide.org

National Guideline Clearinghouse
http://www.guideline.gov

NIH Consensus Development Program
http://consensus.nih.gov

RTI-UNC Evidence-based Practice Center
http://www.rti.org/epc/home.html

US Preventive Services Task Force
http://www.ahrq.gov/clinic/uspstfix.htm

VA Office of Quality and Performance
http://www.oqp.med.va.gov

VA Quality Enhancement Research Initiative (QUERI)
http://www.hsrd.research.va.gov/research/queri

Veterans Evidence-based Research, Dissemination, and Implementation Center (VERDICT)
http://verdict.uthscsa.edu/verdict/default.htm

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